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CDC/ATSDR Procedures for Protection of Human Research Participants: 2003 Revision

The 2003 revision of the *CDC/ATSDR Procedures for Protection of Human Research Participants* is now available. All CDC investigators involved in research involving human participants are expected to be familiar with the contents of this manual. The manual can be found at www.cdc.gov/od/ads/hsrdocs.htm.

Several changes and additions are included in the revised manual. Please note below some of the changes that may affect the review of your research. Some of the other changes or additions are discussed in other parts of this issue of the ADS Newsletter.

- For continuation requests on protocols in which interaction with human subjects is still occurring, a clean copy of the currently approved protocol is now required to be submitted with the form 0.1251 and the current consent documents;
- Studies involving pregnant women, fetuses, and neonates may now be exempted from IRB review

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HSR & IRB Requirements for CDC Career Field Officers (CEFO)

The policy below was recently incorporated into the 2003-revision of the *CDC Procedures for Protection of Human Research Participants.*

"In response to the Secretary, DHHS's directive that CDC assigns an EIS Officer or EIS graduate to every state, the Epidemiology Program Office of CDC created the Career Field Officer Program (CEFO). The goal of the program is to develop a national cadre of EIS-trained CEFOs who will work with states and large local health departments to build epidemiologic and emergency response capacity. Their activities include:

- Providing epidemiologic expertise to state terrorism and emergency response (T&E) planning and policy;
- Providing leadership, training, and technical support for building local epidemiologic capacity;
- Building partnerships with state and local agencies with responsibility for T&E activities;
- Recruiting and supervising new epidemiologists, including EIS Officers.

In essence, CEFOs serve as employees of their respective local and state health departments, and as such, do not submit research to CDC's IRB unless their primary affiliation is identified as CDC on any publication associated with the research. However, they are expected to conduct themselves ethically when carrying out public health activities. When they are engaged in research, CEFOs and their colleagues must obtain approval from an IRB holding an assurance with the Office of Human Subjects Protection (OHRP) and follow the procedures for ethical conduct of research involving human participants described in 45 CFR 46."

Ethical Dilemmas in Public Health

This section normally presents ethical scenarios in public health. In this issue, we will discuss items related to noncompliance with *the Code of Federal Regulation Title 45 "Public Welfare," Part 46 "Protection of Human Subjects,"* (*45CFR46),* also known as the *Common Rule.*

Noncompliance by an Investigator

Common instances of noncompliance by an investigator include

- Not reporting changes in protocol or the informed consent document;
- Misuse or nonuse of informed consent process; and
- Failure to submit protocols to the IRB in a timely fashion.

These problems are often caused by miscommunication and can be easily resolved by an understanding of the requirements and cooperation on the part of the investigator. Some problems are more serious, such as an investigator who ignores or tries to avoid IRB review. Violation such as these place research participants at an unacceptable risk, and immediate action should be taken to halt the research. If an investigator is found to have violated regulatory requirements, the investigator's fitness to conduct the research should be assessed. Any serious or continuing noncompliance with 45CFR46 will be reported to the Office for Human Research Protections (OHRP).

Noncompliance by an IRB

IRB noncompliance occurs whenever the IRB deviates from the duties imposed upon it by 45 CFR 46. Such deviations include failing to ensure that the consent document and process provide sufficient

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A Personal Tribute to Jonathan Mann

Last month marked the fifth anniversary of the SwissAir Flight 111 crash over Nova Scotia on September 2, 1998. Among the 229 people who perished were Jonathan Mann and his wife Mary Lou Clements, both of whom were internationally recognized in their fields. I remember that day as I remember September 11, 2001. I remember exactly where I was, what I was doing, the time of day, and even the weather condition. I had recently moved to Tallahassee, Florida, for my two-year assignment at the Florida Department of Health. It was my first week in the city and my third day in the office when I heard the news of the crash. My feeling was one of immense sadness and loss, the same kind of feeling that I had experienced when I lost my father, three brothers, and my only sister during the Cambodian Killing Fields during 1975─1979.

I first met Jonathan Mann at the 2nd International Conference on Health and Human Rights held at Harvard University in October 1996. I was invited by the student organizers of the conference to speak on student activism regarding health, social justice, and human rights issues, because as a student at the Rollins School of Public Health at Emory University, I was active in promoting an understanding of the important roles these factors play in health. I did not know who Jonathan Mann was before that time, but our paths were bound to cross several more times over the next two years.

In the fall of 1997, he came to Emory to open a health and human rights lecture series, which I co-organized. We discussed various issues then and on several other occasions during his return visits to Atlanta. I remember once asking him how he thought I would make a difference in the world. He advised me to not be afraid to talk about my personal experiences,

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Consultancies

One of the new items discussed in the 2003 revision of the *CDC Procedures for Protection of Human Research Participants* is consultancy. The procedures stipulate when a CDC investigator may participate on a research project, in which CDC does not have a major role, as a consultant.

CDC staff members may be designated as a consultant on human subjects research projects if they meet all of the following criteria listed below:

1. Consultants may not interact or intervene with human subjects for research purposes.
2. Consultants may not possess or obtain personally identifiable information.*
3. Consultants must limit their activities to reviewing and providing advice to the non-CDC investigators regarding scientific activities related to the project (e.g., study design, sampling, recruitment, questionnaire development); the non-CDC investigators must have autonomy in making research decisions (e.g., the consultant cannot mandate items related to study design, protocol, sampling, recruitment, questionnaire development, or similar issues).
4. Consultants may coauthor manuscripts with the non-CDC investigators but generally should not be the first author on any manuscript describing the major and most significant research findings associated with the study.

This guidance is not designed to circumvent the need for CDC Institutional Review Board (IRB) review and approval, which is required for CDC employees serving as collaborating researchers. Instead, when the CIO has determined that a CDC employee serves as a consultant to a research project, it is simultaneously determined that CDC is not engaged in human subjects research. Therefore, CDC IRB review and approval are not required, although each non-CDC institution engaged in the human subjects research must have an assurance with Office for Human Research Protections (OHRP), including local IRB approval, before research activities involving human subjects may begin.

The request for consultant status includes review and approval by the branch (supervisor or Branch Chief), the division (Associate Director for Science or Human Subjects Contact), and the center (Associate Director for Science or Human Subjects Contact). Consultant status, once approved is expected to continue throughout the life of the project. To ensure this, consultancy status will be regularly reviewed.

CDC staff members who wish to be considered consultants on human subjects research studies should contact their CIO HSC.

*In the case where data are existing at the time of involvement of CDC staff, and CDC staff do not have access to identifying information (e.g., there is a written agreement between CDC and the non-CDC institution that unequivocally prohibits release of keys to coded data to CDC), then CDC is considered not engaged in human subjects research.

For more information on consultancy, please refer to the *CDC Procedures for Protection of Human Research Participants* http://www.cdc.gov/od/ads/hsrdocs.htm or contact the CDC Human Subjects Activity, Office of Science Policy and Technology Transfer (OSPTT), at 404-498-3100 or huma@cdc.gov.

Human Subjects Activity Summer 2003 Workshop Series: Informed Consent

Each summer, the CDC Human Subjects Activity (HSA), Office of Science, Policy, and Technology Transfer (OSPTT), offers a "brown bag" workshop series for CDC researchers. This year's topic was informed consent, and it was selected in response to an HSA analysis of factors that slow down protocol approvals at CDC. The workshop curriculum included a review of the required elements of informed consent as well as a structured six-step plan for improved reading comprehension in informed consent documents. Information was also presented about pending Department of Health and Human Service (DHHS) guidance concerning the disclosure of financial conflicts of interest and how this may affect the informed consent process in future research. The workshop concluded with a hands-on exercise in which attendees reviewed and edited a sample consent document and applied practical tips on reading level adjustment, word choice, and formatting. The Informed Consent workshop was presented to 18 research groups between June and August 2003.

The following are tips from the workshop regarding preparation of an informed consent document.

How to Build a Better Informed Consent Document for Research

If you conduct research involving human subjects, you need to know the federal requirements for the informed consent process for study volunteers. Each informed consent document must include the following eight elements:

1. A statement that the project is research, with brief descriptions of its purpose, procedures relevant to human subjects, and expected duration and time commitment for volunteers.
2. A description of foreseeable risks.
3. A description of potential benefits.
4. A description of alternatives to participating in the research.
5. A discussion of means for protecting the confidentiality of research subjects.
6. Contact information for persons the research volunteer may contact for questions about the research project, the rights of research subjects, or harm (if any) resulting from participation in research.
7. A description of the provisions for compensation for harm.
8. A statement that research participation is voluntary.

Tips for Improving the Comprehensibility of Informed Consent Document

Brevity: The informed consent process should focus on essential requirements. A two- or three-page document will generally suffice, particularly for minimal risk studies. Additional information that may be useful to study volunteers, but is not essential to informed consent, should be conveyed through supplementary materials such as fact sheets, FAQs, and brochures.

Clarity: HSA recommends the use of active voice constructions and conversational style whenever possible. Important concepts (such as the voluntary nature of research participation) may be repeated or reinforced throughout the informed consent document. Investigators should use familiar terms whenever possible, explain unfamiliar terms if there are no alternative terms, and use only one meaning for important terms (e.g., the use of "risk" in an informed consent document should be confined to "risks of being in the research," and should not be confused with "adverse effects"). Finally, grade level indicators are useful tools for examining word length, sentence length, and sentence structure, and are standard features of many word processors including MS Word. Frequently, 5th–8th grade reading levels are standard in communications intended for the general U.S. adult population; however, the appropriate reading grade level for an informed consent document is ultimately determined by the study population.

Format: Structured documents help readers find the information they need. In general, informed consent documents should be organized according to the eight required elements described above, and clearly labeled. Labels can be expanded into simple declarative statements or questions that the study volunteer might ask about each requirement. For example, the confidentiality section of an informed consent document could be labeled "How will my privacy be protected in this study?" Additional formatting tips include the use of newspaper style columns (to reduce line length), generous use of white space, and a font size of 12 or greater.

Scripting: Some investigators find it helpful to think of the informed consent document as a script that could be delivered verbally to the research subject. Scripting often simplifies word choices and promotes the use of user-friendly second-person forms. These techniques help the research subject understand what participation in the study means for him or her in a non-abstract way (e.g., "If you decide to volunteer for this study, you will be asked to …..").

Finally, HSA recommends that investigators assess research subjects' comprehension of the informed consent document. A 3–5 point questionnaire, administered prior to signature on the informed consent document, can be used to ensure that research volunteers understand the nature of the research and their role in it. Sample questions may include

1. This study is being done to better understand _____.
2. I can quit my participation in this study _____.
3. This study will involve _____.

Additional information on the informed consent process is available on the HSA website at www.cdc.gov/od/ads/hsrconsent.htm. To schedule an informed consent workshop for your research group, contact Fran Sanden, MS, CIP, Public Health Educator, telephone 404/498-3115, or email to fsanden@cdc.gov.

Upcoming Meetings

- **November 17, 2003**

"Contemporary Issues in Human Research Protections"Co-sponsored by Office for Human Research Protections (OHRP) and Iowa Health

Information and registration - http://www.iowahealth.org/body.cfm?id=354

- **November 15-19, 2003**

American Public Health Association 131st Annual Meeting & Exposition "**Behavior, Lifestyle, and Social Determinants of Health"**

Information and registrations - www.apha.org/meetings/

- **December 4-7, 2003**

Public Responsibility in Medicine and Research (PRIM&R) **"2003 Annual IRB Conference and Related Programs"**

Information and Registration - www.primr.org/IRB03/overview.htm

EPO ADS Newsletter

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particularly those I had during my childhood in Cambodia. He believed that sharing my experiences with others would not only help heal my own wounds, but it will also open people's eyes and minds to the global issues that we seldom encounter in this country.

Internationally, Dr. Mann was known for his passionate fight against global poverty and ill health. He is particularly remembered for his contribution in leading the global movement on health and human rights. He believed that health and human rights are inextricably linked, that promoting and protecting health will also promote human rights and that an infringement on one will also have an impact on the other. He also believed that public health professionals are bound not only to protect health, but also to respect and protect human rights. He felt that every public health program should be considered potentially burdensome on human rights unless proven otherwise. He proposed that public health programs be assessed both for their effectiveness in tackling health problem (public health quality) and for their respect and protection of human rights (human rights quality).

For me these principles were clear and easy to understand, perhaps because of my personal experiences living in refugee camps in Thailand and surviving the Cambodian genocide in the 1970s. I believe as he did that promoting an understanding of health and human rights principles among public health professionals will benefit health and public health practice in general. I also felt that Jonathan Mann was someone who could immediately realize the potential in a person after a brief encounter and could, without much effort, inspire others to work for the common good of humanity. I owe him a great debt of gratitude for helping me realize my own potential, which I hope that I could repay with my continuing effort to promote a better understanding of the linkages between health and human rights. His wisdom continues to guide me in my own work to improve people's health and life.

In the summer of 2001, I initiated the CDC Health and Human Rights Workgroup (HHRW) as part of an ongoing effort to educate CDC staff and other public health professionals about the important linkages between health, public health, and human rights. If you would like to learn more about health and human rights principles and their implications on public health, please visit HHRW Website at http://intranet.cdc.gov/hhrw/.

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information to allow prospective participants to make an informed decision regarding whether to participate in the research, failing to ensure that the research design includes adequate monitoring of the data and any additional safeguards necessary to protect the welfare of particularly vulnerable participants, and failing to conduct continuing review of research at intervals appropriate to the degree of risk. IRBs also breach their regulatory responsibilities by failing to maintain adequate records of IRB business and to hold their meetings with a majority of members present, including a nonscientific member. A demonstrated inability to carry out IRB responsibilities in accordance with 45 CFR 46 can be cause for the suspension or withdrawal of CDCs Assurance.
Reference: *CDC/ATSDR Procedures for Protection of Human Research Participants: 2003* (http://www.cdc.gov/od/ads/hsrdocs.htm)

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if they satisfy the criteria under 45 CFR 46.101;
- For the convened IRB, a quorum will now be defined as a simple majority of the members listed on the roster;
- Sections covering the HIPAA privacy rule have been added (pp. 35, 36─40);
- Investigators will be asked at 50 days after the date the IRB report was sent to them to respond within 10 days, or their protocol may be withdrawn from IRB review.

For more information contact the CDC Human Subjects Activity (HSA), Office of Science Policy and Technology Transfer (OSPTT), at 404-498-3100 or huma@cdc.gov.